

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): LOVAS et al.

Group Art Unit: Unassigned

Serial No.: 10/695,382

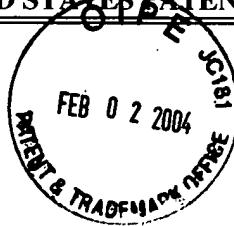
Examiner: Unassigned

Filed: 28 October 2003

Docket No.: 180.0005 0102

Title: NOVEL GnRH ANALOGUES WITH ANTITUMOUR EFFECTS AND PHARMACEUTICAL COMPOSITIONS THEREOF

Confirmation No.: Unknown



Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X Small entity status is entitled to be asserted in the above-identified application.

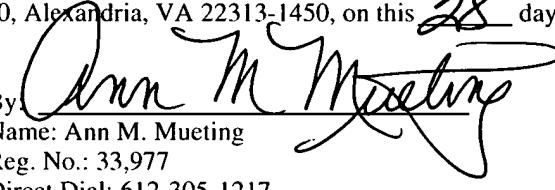
X An itemized return postcard.
X A Petition for Extension of Time for month(s) and a check in the amount of \$ for the required fee.
X An Information Disclosure Statement (2 pgs); copies of 0 applications; 1449 forms (7 pgs); and copy of 1 document cited on the 1449 forms.
 A check in the amount of \$, representing .
 A certified copy of a application, Serial No. , filed , the right of priority of which is claimed under 35 U.S.C. §119.
 Other: .
 Amendment No Additional fee is required. The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$9 =	
Independent Claims				x \$43 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$145 Here →					
Total Additional Claim Fees Required					\$0

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28 day of January, 2004.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By 
Name: Ann M. Mueting
Reg. No.: 33,977
Direct Dial: 612-305-1217
Facsimile: 612-305-1228



PATENT
Docket No.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Lovas et al.) Group Art Unit: Unassigned
Serial No.: 10/695,382) Examiner: Unassigned
Confirmation No.: Unknown)
Filed: 28 October 2003)
For: NOVEL GnRH ANALOGUES WITH ANTITUMOUR EFFECTS AND
PHARMACEUTICAL COMPOSITIONS THEREOF

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

This application is a divisional of U.S. Patent 6,664,369, issued 16 December 2003 (copy enclosed). In accordance with 37 C.F.R. §1.98(d), copies of documents previously cited by or submitted to the U.S. Patent and Trademark Office in connection with Applicants' prior application(s) listed above, are not included herewith.

Information Disclosure Statement

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It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

Respectfully submitted for

LOVAS et al.,

By
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CERTIFICATE UNDER 37 C.F.R. 1.8:

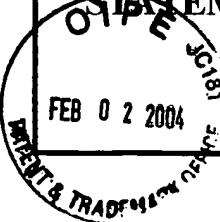
The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28th day of January, 2004

Signature: Kelly Muetting
Printed Name: Kelly J. Muetting

January 28, 2004
Date

AMM/kjm

By: Ann M. Muetting
Ann M. Muetting
Reg. No. 33,977
Direct Dial (612)305-1217

INFORMATION DISCLOSURE STATEMENT  FEB 02 2004	Atty. Docket No.: 180.0005 0102	Serial No.: 10/695,382
	Applicant(s): Lovas et al.	Confirmation No.: Unknown
	Application Filing Date: 10/28/2003	Group: 1653
	Information Disclosure Statement <u>28</u> January 2004 mailed:	

U.S. PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		3,871,964	03/18/1975	Hüper et al.			
		4,116,742	09/26/1978	Firth			
		4,424,079	01/03/1984	Barabas			
		4,833,166	05/23/1989	Grosvenor et al.			
		4,975,420	12/04/1990	Silversides et al.			
		5,593,965	01/14/1997	Lovas et al.			
X		6,664,369	12/16/2003	Lovas et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
		0 368 449 A2, A3	05/16/90	EPO				
		34519	03/28/85	Hungary (with Engl. language abstract)				X
		212 661 A	11/28/96	Hungary			X	
		212 662 A	11/28/96	Hungary			X	
		9-508142	08/19/97	Japan (with Engl. language abstract)				X
		WO 96/04927	02/22/96	PCT				

EXAMINER	Date Considered
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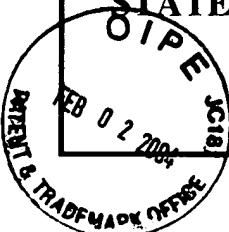
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OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
		Azori et al., "Synthesis, elimination, and whole-body distribution of ¹⁴ C-labelled drug carrier," <u>Die Makromolekulare Chemie</u> , <u>187</u> (2):297-302 (1986).
		Bokser et al., "Inhibition of pituitary-gonadal axis in mice by long-term administration of D-Trp-6-LHRH microcapsules," <u>Journal of Reproduction and Fertility</u> , <u>85</u> (2):569-574 (1989).
		"Breast Cancer," American Cancer Society [online]. [Retrieved March 18, 1996]. Retrieved from the Internet: <URL: http://www.cancer.org/breast.html >, 2 pages.
		Butler, "Synthesis and Properties of Novel Polyanions of Potential Antitumor Activity," <u>Journal of Macromolecular Science - Chemistry</u> , <u>A13</u> (3):351-368 (1979).
		Cailleau et al., "Breast Tumor Cell Lines From Pleural Effusions," <u>Journal of the National Cancer Institute</u> , <u>53</u> (3):661-674 (1974).
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		Edsall et al., eds., "IUPAC-IUB Combined Commission on Biochemical Nomenclature Abbreviations and Symbols for Chemical Names of Special Interest in Biological Chemistry, Revised Tentative Rules (1965)," <u>Journal of Biological Chemistry</u> , <u>241</u> (3):527-533 (1966).
		Eidne et al., "Gonadotropin-Releasing Hormone Binding Sites in Human Breast Carcinoma," <u>Science</u> , <u>229</u> (4717):989-991 (1985).
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		Gaál et al., "Immunomodulatory Effect of Synthetic Branched Polypeptides. II.," <u>Journal of Biological Response Modifiers</u> , <u>5</u> (2):148-159 (1986).
		Glass, John, D., "Enzymatic Manipulation of Protecting Groups in Peptide Synthesis," <u>The Peptides</u> , Udenfriend et al., eds., Academic Press, Inc., San Diego, Title page, publication page, table of contents, pp. 178 and 253 (1987).

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		Gros, "Biological Activity," <u>Encyclopedia of Polymer Science and Engineering</u> , Vol. 2, John Wiley & Sons, Inc., New York, Title page, publication page, and pages 243-267 (1985).
		Harris et al., "Gonadotropin-releasing Hormone Gene Expression in MDA-MB-231 and ZR-75-1 Breast Carcinoma Cell Lines," <u>Cancer Research</u> , 51(10):2577-2581 (1991).
		Holden, ed., "Tamoxifen Labeled Carcinogen," <u>Science</u> , 271(5254):1367 (1996).
		Kaighn et al., "Establishment and characterization of a human prostatic carcinoma cell line (PC-3)," <u>Investigative Urology</u> , 17(1):16-23 (1979).
		Kálnay et al., "Influence on antiproliferative activity of structural modification and conjugation of gonadotropin-releasing hormone (GnRH) analogues," <u>Cell Proliferation</u> , 33(5):275-285 (October, 2000).
		Kaufmann et al., "Goserelin, a Depot Gonadotropin-Releasing Hormone Agonist in the Treatment of Premenopausal Patients With Metastatic Breast Cancer," <u>Journal of Clinical Oncology</u> , 7(8):1113-1119 (1989).
		King et al., "Structure of Chicken Hypothalamic Luteinizing Hormone-releasing Hormone: I. Structural Determination on Partially Purified Material," <u>Journal of Biological Chemistry</u> , 257(18):10722-10728 (1982).
		Kovács et al., "Effects of Long-Term Administration of a Superactive Agonistic and an Antagonistic GnRH Analog on the Pituitary-Gonad System," <u>Peptides</u> , 10(5):925-931 (1989).
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		Mező et al., "GnRH analogs and their conjugates with enhanced antitumor activity," <u>Proceedings of the Twenty Third European Peptide Symposium</u> , September 4-10, 1994, Braga, Portugal, <u>Peptides</u> 1994, pages 763-764 (1995).

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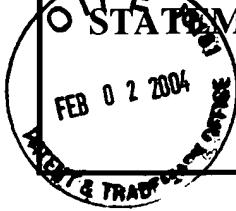
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		Mezo et al., "GnRH analogs and their conjugates with enhanced antitumor activity," Proceedings of the European Peptide Symposium, September 23, 1994, <u>Peptides</u> , pages 763-764, <u>Chemical Abstracts</u> , 125(25): abstract no. 316399 (1996).
		Mezö et al., "Synthesis, Conformation, Biodistribution, and Hormone-Related <i>in Vitro</i> Antitumor Activity of a Gonadotropin-Releasing Hormone Antagonist-Branched Polypeptide Conjugate," <u>Bioconjugate Chemistry</u> , 7(6):642-650 (1996).
		Mezö et al., "Properties of GnRH conjugates <i>in vivo</i> ," Proceedings of the Fifteenth American Peptide Symposium, June 14-19, Nashville, <u>Peptides: Frontiers of Peptide Science</u> , Tam et al., eds., Kluwer Academic Publishers, Boston, pages 561-562 (1997).
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		National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, GenBank Accession No. AAB25536, "Gonadotropin-releasing hormone, GnRH-III [Petromyzon marinus=sea lampreys, brain, Peptide, 10 aa]," [online]. Bethesda, MD [retrieved on June 20, 2001]. Retrieved from the Internet:<URL: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=Protein&list_uids=266203&dopt=DocSum , 1 page.
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		(Abstract) Nishida et al., "Establishment of a New Human Endometrial Adenocarcinoma Cell Line, Ishikawa Cells, Containing Estrogen and Progesterone Receptors," Japanese language journal article with English language synopsis, <u>Acta Obstetrica et Gynaecologica Japonica</u> , 37(7):1103-1111 (1985).
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		Reddy et al., "Preparation of potentially electroactive thallium polymers derived from the acidic copolymers of maleic anhydride," <u>Polymer</u> , <u>25</u> (1):115-120 (1984).
		Schally, "The use of LHRH analogs in gynecology and tumor therapy," <u>General Gynecology</u> , <u>vol. 6</u> , Belfort et al., eds., Parthenon Publishing, Carnforth, England, Title page, publication page, table of contents, and pages 3-22 (1989).
		Scott et al., "Factors Influencing the Response of MCF-7 Cells to an Agonist of Luteinising Hormone-releasing Hormone," <u>European Journal of Cancer</u> , <u>27</u> (11):1458-1461 (1991).
		Segal-Abramson et al., "Guanine nucleotide modulation of high affinity gonadotropin-releasing hormone receptors in rat mammary tumors," <u>Molecular and Cellular Endocrinology</u> , <u>85</u> (1-2):109-116 (1992).
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		Sharoni et al., "Inhibition of growth of human mammary tumor cells by potent antagonists of luteinizing hormone-releasing hormone," <u>Proceedings of the National Academy of Sciences USA</u> , <u>86</u> (5):1648-1651 (1989).
		Sherwood et al., "Characterization of a teleost gonadotropin-releasing hormone," <u>Proceedings of the National Academy of Sciences USA</u> , <u>80</u> (9):2794-2798 (1983).
		Soule et al., "A Human Cell Line From a Pleural Effusion Derived From a Breast Carcinoma," <u>Journal of the National Cancer Institute</u> , <u>51</u> (5):1409-1416 (1973).
		Sower et al., "Primary Structure and Biological Activity of a Third Gonadotropin-Releasing Hormone from Lamprey Brain," <u>Endocrinology</u> , <u>132</u> (3):1125-1131 (1993).
		Steel et al., "Improved Immune-Suppression Techniques for the Xenografting of Human Tumours," <u>British Journal of Cancer</u> , <u>37</u> (2):224-230 (1978).
		Szepeshazi et al., "Growth inhibition of estrogen independent MXT mouse mammary carcinomas in mice treated with an agonist or antagonist of LH-RH, an analog of somatostatin, or a combination," <u>Breast Cancer Research and Treatment</u> , <u>21</u> (3):181-192 (1992).

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		“Table 1. Breast Cancer incidence in women in Australia, 1990,” National Breast Cancer Centre, National Health and Medical Research Council [online]. Sydney, Australia, October 11, 1995 [retrieved March 18, 1996]. Retrieved from the Internet: <URL: http://www.nbcc.org.au/pages/table1.htm >, 1 page.
		“Table 2. Breast Cancer Incidence Worldwide,” National Breast Cancer Centre, National Health and Medical Research Council [online]. Sydney, Australia, October 10, 1995 [retrieved March 23, 1996]. Retrieved from the Internet: <URL: http://www.nbcc.org.au/pages/table2.htm >, 1 page.
		“Table 3. Estimates of breast cancer incidence and mortality in women in some countries of the European Union and in Australia,” National Breast Cancer Centre, National Health and Medical Research Council [online]. Sydney, Australia, October 11, 1995 [retrieved March 18, 1996]. Retrieved from the Internet: <URL: http://www.nbcc.org.au/pages/table3.htm >, 1 page.
		Tabor et al., eds., “IUPAC-IUB Commission on Biochemical Nomenclature Symbols for Amino-Acid Derivatives and Peptides, Recommendations (1971),” <u>Journal of Biological Chemistry</u> , 247(4):977-983 (1972).
		Vincze et al., “Effect of LHRH agonist on estradiol sensitive and insensitive human breast cancer cells,” Abstract A4.116.04, 15 th International Cancer Congress, Hamburg, August 16-22, <u>Journal of Cancer Research and Clinical Oncology</u> , 116:427 (1990).
		Vincze et al., “Influence of luteinizing hormone-releasing hormone agonists on human mammary carcinoma cell lines and their xenografts,” <u>Journal of Steroid Biochemistry and Molecular Biology</u> , 38(2):119-126 (1991).
		Vincze et al., “Direct effect of GNRH agonists and antagonists on estradiol-dependent and -independent human mammary cancer cells,” Abstract, <u>Cell Proliferation</u> , 25:518 (1992).
		Vincze et al., “Antitumour effect of a gonadotropin-releasing-hormone antagonist (MI-1544) and its conjugate on human breast cancer cells and their xenografts,” <u>Journal of Cancer Research and Clinical Oncology</u> , 120:578-584 (1994).
		Weinbauer et al., “LH-RH Antagonists: State of the Art and Future Perspectives,” <u>Recent Results in Cancer Research</u> , 124:113-136 (1992).

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		Yano et al., "Inhibition of growth of MCF-7 MIII human breast carcinoma in nude mice by treatment with agonists or antagonists of LH-RH," <u>Breast Cancer Research and Treatment</u> , 21(1):35-45 (1992).

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